

1 | MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

2 |  
3 | **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**  
4 | **OPEN HEART SURGERY SERVICES**  
5 |

6 | (By the authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts  
7 | of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 | sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)  
9 |

10 | **Section 1. Applicability**

11 |  
12 | Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects  
13 | approved and certificates of need issued under Part 222 of the Code which involve open heart surgery  
14 | services.  
15 |

16 | (2) Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.  
17 |

18 | (3) The Department shall use sections 3, 4, 5, 6, 8, and 9, as applicable, in applying Section  
19 | 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.  
20 |

21 | (4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section  
22 | 333.22225(2)(c) of the Michigan Compiled Laws.  
23 |

24 | (5) THE DEPARTMENT SHALL USE SECTION 5 IN APPLYING SECTION 22215(1)(B) OF THE  
25 | CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.  
26 |

27 | **Section 2. Definitions**

28 |  
29 | Sec. 2. (1) FOR PURPOSES OF A~~s used in~~ these standards:  
30 |

31 | (a) "Adult open heart surgery" means open heart surgery offered and provided to individuals age 15  
32 | and older AS DEFINED IN SUBSECTION (I).  
33 |

34 | (b) "Cardiac surgical team" means the designated specialists and support personnel who  
35 | consistently work together in the performance of open heart surgery.

36 | (c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
37 | Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

38 | (d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et  
39 | seq. of the Michigan Compiled Laws.

40 | (e) "Department" means the Michigan Department Of Community Health (MDCH).

41 | (f) "ICD-9-CM code" means the disease codes and nomenclature found in the International  
42 | Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on  
43 | Professional and Hospital Activities for the U.S. National Center for Health Statistics.

44 | (g) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
45 | and 1396r-8 to 1396v.

46 | (h) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health  
47 | and Hospital Association or successor organization. The data base consists of inpatient discharge  
48 | records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for  
49 | a specific calendar year.

50 | (i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic  
51 | great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac  
52 | and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and  
53 | oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These  
54 | procedures may be performed off-pump (beating heart), although a heart-lung pump is still available  
55 | during the procedure.

55 | (J) "OPEN HEART SURGICAL CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM  
56 | DURING WHICH ONE OR MORE OPEN HEART SURGERY PROCEDURES ARE PERFORMED.

57 | (K) "Open heart surgery service" means a hospital program that is staffed with surgical teams and  
58 | other support staff for the performance of open heart surgical procedures. An open heart surgery service  
59 | performs open heart surgery procedures on an emergent, urgent and scheduled basis.

60 | (L) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and  
61 | children age 14 and ~~YOUNGER~~below, and to other individuals with congenital heart disease as defined  
62 | by the ICD-9-CM codes of 745.0 through 747.99.

63 | (M) "Planning area" means the groups of counties shown in Section 10.

64 |  
65 | (2) The definitions in Part 222 shall apply to these standards.  
66 |

67 | **Section 3. Requirements for ALL APPLICANTS PROPOSING TO INITIATE OPEN HEART**  
68 | **SURGERY SERVICES**~~Approval -- all applicants~~

69 |  
70 | Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new  
71 | service shall ~~BE OPERATING OR APPROVED TO OPERATE~~ have in place, or meet the CON review  
72 | ~~standards for initiation of~~ diagnostic and therapeutic adult or pediatric cardiac catheterization services,  
73 | respectively.  
74 |

75 | (2) A hospital proposing to initiate open heart surgery as a new service shall have a written  
76 | consulting agreement with a hospital which has an existing active open heart surgery service performing  
77 | a minimum of ~~400350~~ open heart surgical ~~CASES~~procedures per year FOR 3 CONSECUTIVE YEARS.  
78 | The agreement must specify that the existing service shall, for the first 3 years of operation of the new  
79 | service, provide the following services to the applicant hospital:

80 | (a) Receive and make recommendations on the proposed design of surgical and support areas that  
81 | may be required;

82 | (b) Provide staff training recommendations for all personnel associated with the new proposed  
83 | service;

84 | (c) Provide recommendations on staffing needs for the proposed service; and

85 | (d) Work with the medical staff and governing body to design and implement a process that will at  
86 | least annually measure, evaluate, and report to the medical staff and governing body, the clinical  
87 | outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and  
88 | (iv) Infection rates.  
89 |

90 | ~~(3) An applicant shall provide verification of Medicaid participation at the time the application is~~  
91 | ~~submitted to the Department. If the required documentation is not submitted with the application on the~~  
92 | ~~designated application date, the application will be deemed filed on the first applicable designated~~  
93 | ~~application date after all required documentation is received by the Department.~~

94 |  
95 | **Section 4. Requirements for approval -- all applicants for adult open heart surgery services**

96 |  
97 | ~~Sec. 4. (3)~~ An applicant proposing to initiate adult (~~non-pediatric~~) open heart surgery as a new  
98 | service shall demonstrate ~~that~~ 300 adult open heart surgical ~~CASES~~procedures BASED ON ~~result from~~  
99 | ~~application of~~ the methodology SET FORTH~~described~~ in Section 8.  
100 |

101 | **Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services**

102 |  
103 | ~~Sec. 5. (4)~~ An applicant proposing to initiate pediatric open heart surgery as a new service shall  
104 | demonstrate ~~that~~ 100 pediatric open heart surgical ~~CASES~~procedures BASED ON ~~result from application~~  
105 | ~~of~~ the methodology SET FORTH~~described~~ in Section 9.  
106 |

107 | **SECTION 4. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN**  
108 | **EXISTING OPEN HEART SURGERY SERVICE**

109 SEC. 4. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED  
110 TO PERFORM OPEN HEART SURGERY SERVICES MAY ALSO ACQUIRE THE EXISTING OPEN  
111 HEART SURGERY SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS  
112 ALL OF THE FOLLOWING:  
113

114  
115 (1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING OPEN HEART SURGERY  
116 SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL NOT BE REQUIRED TO  
117 BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF  
118 ACQUISITION. THE OPEN HEART SURGERY SERVICE SHALL BE OPERATING AT THE  
119 APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS IN  
120 THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY  
121 THEREAFTER.  
122

123 (2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION  
124 OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE  
125 STANDARDS SHALL BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME  
126 REQUIREMENTS, AS SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS, ON THE DATE AN  
127 APPLICATION IS SUBMITTED TO THE DEPARTMENT.  
128

129 (3) THE APPLICANT AGREES TO OPERATE THE OPEN HEART SURGERY SERVICE IN  
130 ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN  
131 SECTION 7 OF THESE STANDARDS.  
132

#### 133 **SECTION 5. REQUIREMENTS FOR ALL APPLICANTS**

134  
135 SEC 5. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN  
136 APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL  
137 CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT  
138 WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES, IF A CON IS APPROVED.  
139

#### 140 **Section 6. Requirements for MIDB data commitments**

141  
142 Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart  
143 surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:  
144

145 (1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart  
146 surgery services shall not use any of its adult MIDB data in support of any other application for adult open  
147 heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB  
148 data were used to support. -AFTER THE 7-YEAR PERIOD:

149 (A) A HOSPITAL(S) MAY ONLY COMMIT ITS ADULT MIDB DATA IN SUPPORT OF ANOTHER  
150 APPLICATION FOR ADULT OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN  
151 INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL  
152 INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN  
153 HEART SURGERY SERVICES, OR;

154 (B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS ADULT MIDB DATA AND  
155 WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE  
156 PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF ADULT  
157 MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART SURGERY  
158 SERVICE.  
159

160 (2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric  
161 open heart surgery services shall not use any of its pediatric MIDB data in support of any other

162 application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart  
163 surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD:

164 (A) A HOSPITAL(S) MAY ONLY COMMIT ITS PEDIATRIC MIDB DATA IN SUPPORT OF  
165 ANOTHER APPLICATION FOR PEDIATRIC OPEN HEART SURGERY SERVICES IF THEY HAVE  
166 EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT  
167 ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO  
168 INITIATE OPEN HEART SURGERY SERVICES, OR;

169 (B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS PEDIATRIC MIDB DATA AND  
170 WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE  
171 PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF  
172 PEDIATRIC MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART  
173 SURGERY SERVICE.

174  
175 (3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart  
176 surgery service or have a valid CON issued under ~~former Part 221 or~~ Part 222 to operate an adult or  
177 pediatric open heart surgery service.

178  
179 (4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to  
180 which MIDB data is being proposed to be committed.

181  
182 (5) The hospital(s) committing MIDB data to a CON application has completed the departmental  
183 form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges  
184 associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the  
185 MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

186  
187 (6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the  
188 date the Director makes the final decision on that application, under Section 22231~~(9)~~ of the Code, being  
189 Section 333.22231~~(9)~~ of the Michigan Compiled Laws.

## 191 **Section 7. Project delivery requirements -- terms of approval for all applicants**

192  
193 Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance  
194 with the following terms of CON approval:

195 (a) Compliance with these standards.

196 (b) Compliance with applicable operating standards.

197 (c) Compliance with the following quality assurance standards:

198 (i) The open heart surgery service shall be operating at an annual level of 300 adult open heart  
199 surgical CASESprocedures or 100 pediatric open heart surgical CASESprocedures, as applicable, by the  
200 end of the third 12 full months of operation, AND ANNUALLY THEREAFTER.

201 (ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery  
202 CASESprocedures, as the attending surgeon, shall perform a minimum of 7550 adult open heart surgery  
203 CASESprocedures per year. The annual case load for a physician means adult open heart surgery  
204 CASESprocedures performed by that physician, as the attending surgeon, in any hospital or combination  
205 of hospitals.

206 (iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to  
207 permit regular scheduled hours of operation and continuous 24 hour on-call availability.

208 (iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for  
209 emergency CASESprocedures 24 hours a day, 7 days a week.

210 (v) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years  
211 of operation and continue to participate annually thereafter.

212 (d) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

213 (i) provide open heart surgery services to all individuals based on the clinical indications of need for  
214 the service and not on ability to pay or source of payment; and

215 (ii) maintain information by source of payment to indicate the volume of care from each source  
216 provided annually.

217 Compliance with selective contracting requirements shall not be construed as a violation of this term.

218 (e) The applicant shall prepare and present to the medical staff and governing body reports  
219 describing activities in the open heart surgery service including complication rates and other morbidity  
220 and mortality data.

221 (f) The applicant shall participate in a data collection network established and administered by the  
222 Department or its designee. The data may include but is not limited to annual budget and cost  
223 information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as  
224 well as the volume of care provided to patients from all payor sources. The applicant shall provide the  
225 required data in a format established by the Department and in a mutually agreed upon media. The  
226 Department may elect to verify the data through on-site review of appropriate records.

227 (G) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE  
228 DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.  
229 THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A  
230 SUMMARY REPORT AS SPECIFIED BY THE DEPARTMENT. THE APPLICANT SHALL PROVIDE  
231 THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE.  
232 THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE  
233 REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE  
234 QUALITY. THE APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY SPECIFIED BY  
235 THE DEPARTMENT UPON INITIATION OF THE SERVICE. PARTICIPATION SHALL CONTINUE  
236 ANNUALLY THEREAFTER. THE OUTCOMES DATABASE MUST UNDERGO STATEWIDE AUDITING.

237 (H) AN APPLICANT THAT FAILS TO COMPLY WITH THE QUALITY ASSURANCE STANDARDS  
238 UNDER SUBSECTION (C) SHALL BE REQUIRED TO PROVIDE ITS QUALITY AND RISK ADJUSTED  
239 OUTCOMES DATA FROM THE DATA REGISTRY TO THE DEPARTMENT, OR ITS DESIGNEE, AS  
240 PART OF THE DEPARTMENT'S ENFORCEMENT AND COMPLIANCE ACTIVITIES.

241 (g) The applicant shall provide the Department with a notice stating the date on which the first  
242 approved service is performed and such notice shall be submitted to the Department consistent with  
243 applicable statute and promulgated rules.

244  
245 (2) The agreements and assurances required by this section shall be in the form of a certification  
246 AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT~~authorized by the governing body of~~  
247 ~~the applicant.~~

248  
249 **Section 8. Methodology for computing the number of adult open heart surgical CASESprocedures**  
250

251 Sec. 8. (1) An applicant shall apply the methodology set forth in this section for computing the  
252 number of adult open heart surgical CASESprocedures. In applying discharge data in the methodology,  
253 each applicable inpatient record shall be used only once. This methodology shall utilize only the inpatient  
254 discharges that have one or more of the cardiac diagnoses in Subsection (2). In applying this  
255 methodology, the following steps shall be taken in sequence:

256 (a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan  
257 Inpatient Data Base available to the Department, an applicant shall identify the discharges that were from  
258 patients aged 15 years and older. These discharges shall be considered "adult discharges."

259 (b) Using the "adult discharges" identified in Subdivision (a), an applicant shall count the number of  
260 discharges with a principal diagnosis corresponding to each of the first six categories (Groups A through  
261 F) of ICD-9-CM codes listed in Subsection (2). When a patient has a principal diagnosis which falls into  
262 one of these six groups (exclude Other Heart Conditions), then they shall be categorized by that  
263 diagnosis and their case shall be removed from the data to be used in Subdivisions (c), (d) and (e) so that  
264 each applicable inpatient record shall be counted only once.

265 (c) The procedure in this subdivision shall be used to determine in which diagnosis group each  
266 appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used  
267 to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in  
268 Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with

269 | ~~the first category of Valves (Group A: ICD-9-CM codes 394.0-397.99 and 424.0-424.99)~~ and shall search  
270 | through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record  
271 | has a non-principal diagnosis code for this grouping, it shall be assigned to ~~the Valve g~~Group A and shall  
272 | be removed from all subsequent search actions. The remaining inpatient records shall then be searched  
273 | for the presence of the ~~Valve~~GROUP A codes. After all the inpatient records with ~~Valve codes~~GROUP A  
274 | have been removed, the above procedure shall be repeated for each of the remaining five groups  
275 | (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient  
276 | records for codes representing ~~the Congenital Anomalies (Group B: ICD-9-CM codes 745.0-747.99).~~  
277 | NOTE: The above procedure shall not apply to ~~the All Other Heart Conditions category (Group G).~~

278 | (d) Add the count of the number of records for each principal diagnosis group (separately) that was  
279 | identified under Subdivision (b) with the count of the number of records for its respective non-principal  
280 | diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first  
281 | six diagnostic groups (excluding ~~All Other Heart Conditions~~ – Group G).

282 | (e) Using the remaining discharge data, an applicant shall count the discharges that were from  
283 | patients that have a principal diagnosis or any of the first four non-principal diagnoses using the  
284 | ICD-9-CM codes for ~~the All Other Heart Conditions category (Group G)~~ listed in Subsection (2).

285 | (f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its  
286 | corresponding Adult Open Heart Utilization Weight and add the products together to produce the number  
287 | of adult open heart surgical CASEProcedures for the applicant.

288 |  
289 | (2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:  
290 |

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL ~~CASES~~PROCEDURES

Group	Major ICD-9-CM Code Group	Category	Adult Open Heart Utilization Weights
<del>A</del>	<del>394 - 397.9</del>	<del>Valves</del>	<del>.0808</del>
	<del>424 - 424.99</del>		
<del>AB</del>	745 - 747.99	Congenital Anomalies	<u>.125246.0766</u>
<del>B</del>	<del>394 - 397.9</del>	<del>VALVES</del>	<del>.086804</del>
	<del>424 - 424.99</del>		
<del>C</del>	<del>410 - 410.99</del>	<del>ACUTE MYOCARDIAL INFARCT</del>	<del>.071210</del>
<del>DG</del>	414 - 414.99	Other Chronic Ischemic	<u>.062683.0632</u>
<del>ED</del>	411 - 411.99	Other Acute & Sub Acute Ischemic	<u>.012538.0510</u>
<del>E</del>	<del>410 - 410.99</del>	<del>Acute Myocardial Infarct</del>	<del>.0400</del>
F	413 - 413.99	Angina & Chest Pain	<u>.000546.0102</u>
	786.5 - 786.59		
<hr/>			
G	<u>164.1, 212.7</u>	All Other Heart Conditions	<u>.002085.0029</u>
	390 - 393		
	398 - 405.99		
	412, 415 - 423.9		
	425 - 429.99		
	<u>441.01, 441.03</u>		
	<u>441.1, 441.2</u>		
	<u>441.6, 441.7</u>		
	<u>785.51, 901.0</u>		
	<u>996.02, 996.03</u>		

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Subsection (2) are based on the work of the ~~BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development, Michigan Department of ~~COMMUNITY~~Public Health, utilizing the ~~2005-1986~~ Michigan Inpatient Data Base.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

**Section 9. Methodology for computing the number of pediatric open heart surgical ~~CASES~~procedures**

Sec. 9. (1) An applicant shall apply the methodology set forth in this section for computing the number of pediatric open heart surgical ~~CASES~~procedures. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall count the discharges that were from

345 patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the  
 346 ICD-9-CM codes listed in the "Congenital Anomalies" category in Subsection (2). Each identified record  
 347 shall be counted only once so that no record is counted twice. An applicant shall remove these cases  
 348 from the discharge data.

349 (b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that  
 350 were from patients aged 14 years and younger. These discharges shall be known as the "pediatric  
 351 discharges."

352 (c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number  
 353 of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM  
 354 codes listed in the "Other Heart" category in Subsection (2). Discharge records which do not have one or  
 355 more of the Other Heart codes listed in Subsection (2) shall not be used. Each identified record shall be  
 356 counted only once so that no record is counted twice.

357 (d) An applicant shall multiply the count for the "Congenital" and "Other Heart" categories by the  
 358 corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the  
 359 number of pediatric open heart surgical CASES procedures for the applicant.

360  
 361 (2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:

362  
 363 | DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES PROCEDURES

365 Major ICD-9-CM	366 <u>Grouping</u>	367 <u>Category</u>	368 <u>Pediatric Open Heart</u>
			369 <u>Utilization Weights</u>
370	745.0-747.99	Congenital Anomalies	<u>.210888-1286</u>
371	<u>164.1, 212.7</u>	Other Heart	<u>.042973-0147</u>
372	390-429.99		
373	<u>441.01, 441.03</u>		
374	<u>441.1, 441.2</u>		
375	<u>441.6, 441.7</u>		
376	<u>785.51</u>		
377	786.5-786.59		
378	<u>901.0, 996.02</u>		

379 (3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights are based on the  
 380 work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS former Division of Planning and  
 381 Policy Development, Michigan Department of COMMUNITY Public Health, utilizing the 2005-1986  
 382 Michigan Inpatient Data Base.

383  
 384 (4) Each applicant must provide access to verifiable hospital-specific data and documentation using  
 385 a format established by the Department and in a mutually agreed upon media.

386  
 387 **Section 10. Planning Areas**

388  
 389 Sec. 10. Counties assigned to each planning area are as follows:

391 <u>PLANNING AREA</u>	392 <u>COUNTIES</u>		
393 1	LIVINGSTON	MONROE	ST. CLAIR
394	MACOMB	OAKLAND	WASHTENAW
395	WAYNE		
396			
397 2	CLINTON	HILLSDALE	JACKSON
398	EATON	INGHAM	LENAWEE

399				
400	3	BARRY	CALHOUN	ST. JOSEPH
401		BERRIEN	CASS	VAN BUREN
402		BRANCH	KALAMAZOO	
403				
404	4	ALLEGAN	MASON	NEWAYGO
405		IONIA	MECOSTA	OCEANA
406		KENT	MONTCALM	OSCEOLA
407		LAKE	MUSKEGON	OTTAWA
408				
409	5	GENESEE	LAPEER	SHIAWASSEE
410				
411	6	ARENAC	HURON	ROSCOMMON
412		BAY	IOSCO	SAGINAW
413		CLARE	ISABELLA	SANILAC
414		GLADWIN	MIDLAND	TUSCOLA
415		GRATIOT	OGEMAW	
416				
417				

418		<del>7</del>	ALCONA	CRAWFORD	MISSAUKEE
419			ALPENA	EMMET	MONTMORENCY
420			ANTRIM	GD TRAVERSE	OSCODA
421			BENZIE	KALKASKA	OTSEGO
422			CHARLEVOIX	LEELANAU	PRESQUE ISLE
423			CHEBOYGAN	MANISTEE	WEXFORD
424					
425		8	ALGER	GOGEBIC	MACKINAC
426			BARAGA	HOUGHTON	MARQUETTE
427			CHIPPEWA	IRON	MENOMINEE
428			DELTA	KEWEENAW	ONTONAGON
429			DICKINSON	LUCE	SCHOOLCRAFT

430

431 **Section 11. Application of Rule 325.9403**

432

433 ~~— Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under~~  
434 ~~these standards or standards that became effective on December 5, 1988 shall expire 1 year from its~~  
435 ~~effective date, unless the project is initiated. One 6-month extension may be granted by the Department~~  
436 ~~if the applicant shows that substantial progress toward initiation of the approved open heart surgery~~  
437 ~~service has been made and an obligation for capital expenditure, if any, will occur within the extended~~  
438 ~~time period.~~

439

440 ~~— (2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery~~  
441 ~~procedure is performed.~~

442

443 **Section 1142. Effect on prior planning policies; comparative reviews**

444

445 Sec. 1142. (1) These CON Review Standards supersede and replace the CON Review Standards for  
446 Open Heart Surgery Services approved by the CON Commission on MARCH 9, 2004~~March 11, 2003~~ and  
447 effective on JUNE 4, 2004~~May 12, 2003~~.

448

449 ~~(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan~~  
450 ~~(SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers~~  
451 ~~shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals~~  
452 ~~recognized by the Department as Level II providers under Part 221 may continue to provide Level II~~  
453 ~~cardiac services consistent with the 1985-90 State Medical Facilities Plan.~~

454

455 ~~— (23) Projects reviewed under these standards shall not be subject to comparative review.~~